LISTING OF THE CLAIMS:

This Listing of the Claims will replace all prior versions, and listings, of the claims in the present application.

1-69 (canceled)

70. (new) A sustained-release oral dosage form comprising an extruded blend of:

hydromorphone or a pharmaceutically acceptable salt thereof;

one or more hydrophobic materials selected from the group consisting of alkylcelluloses, acrylic and methacrylic acid polymers and copolymers, shellac, zein, hydrogenated castor oil, hydrogenated vegetable oil, and mixtures thereof; and

one or more hydrophobic fusible carriers having a melting point from about 30 °C to about 200 °C and selected from the group consisting of natural or synthetic waxes, fatty acids, fatty alcohols, and mixtures thereof,

wherein the extrude blend is divided into a unit dose containing an effective amount of hydromorphone to render a desired therapeutic effect and providing a sustained-release of hydromorphone for a time period from about 8 to about 24 hours,

and wherein the oral dosage form, when containing about 8 mg hydromorphone or its pharmaceutically acceptable salt, provides an in-vivo plasma concentration versus time curve (in the fasted state) having an AUC from about 15.83 to about 19.23 ng·hour/ml, which is about 96-132% of the AUC observed when an immediate release formulation of the same dosage is administered, a C_{max} from about 0.52 to about 0.76 ng/ml, which is about 16-21% of the C_{max} observed when an immediate release formulation of the same dosage is administered, and a T_{max} from about 3.9 to about 6.8 hours, which is about 557-971% of the T_{max} observed when an immediate release formulation of the same dosage is administered.

71. (new) A sustained-release oral dosage form comprising an extruded blend of:

hydromorphone or a pharmaceutically acceptable salt thereof;

one or more hydrophobic materials selected from the group consisting of alkylcelluloses, acrylic and methacrylic acid polymers and copolymers, shellac, zein, hydrogenated castor oil, hydrogenated vegetable oil, and mixtures thereof; and

one or more hydrophobic fusible carriers having a melting point from about 30 °C to about 200 °C and selected from the group consisting of natural or synthetic

waxes, fatty acids, fatty alcohols, and mixtures thereof,

wherein the extrude blend is divided into a unit dose containing an effective amount of hydromorphone to render a desired therapeutic effect and providing a sustained-release of hydromorphone for a time period from about 8 to about 24 hours,

and wherein the oral dosage form, when containing about 8 mg hydromorphone or its pharmaceutically acceptable salt, provides an in-vivo plasma concentration versus time curve (in the fed state) having an AUC from about 16.55 to about 21.47 ng·hour/ml, a C_{max} of from about 0.65 to about 0.93 ng/ml, and a T_{max} of from about 1.9 to about 4.1 hours.

72. (new) The oral dosage form of claim 70 or 71, wherein the extruded blend is formed by mixing the hydromorphone or its pharmaceutically acceptable salt, the one or more hydrophobic materials, and the one or more hydrophobic fusible carriers in an extruder to form the blend and extending the blend through the extruder.

73. (new) The oral dosage form of claim 72, wherein the hydromorphone or its pharmaceutically acceptable salt, the one or more hydrophobic materials, and the one or more hydrophobic fusible carriers enter said extruder in powder form.

74. (new) The oral dosage form of claim 72, wherein the hydromorphone or its pharmaceutically acceptable salt, the one or more hydrophobic materials, and the one or more hydrophobic fusible carriers, all in powder form, are mixed to form a powder mixture prior to entering the extruder.

75. (new) The oral dosage form of claim 72, wherein the blend is subjected to sufficient amount of heat to sufficiently soften the blend during the extrusion process.

76. (new) The oral dosage of claim 72, wherein the extruded blend is substantially non-porous.

77. (new) The oral dosage form of claim 72 wherein the extrudate has a diameter of from about 0.1 to about 5 mm.

78. (new) The oral dosage form of claim 72, wherein the extrudate comprises a strand-shaped matrix cut into multi-particulates having a length of from about 0.1 to about 5 mm in length.

79. (new) The oral dosage form of claim 78, wherein a unit dose comprising an effective amount of the multi-particulates is compressed into a tablet.

80. (new) The oral dosage form of claim 78, wherein a unit dose comprising an effective amount of the multi-particulates is contained within a gelatin capsule.

81. (new) The oral dosage form of claim 72, wherein the hydrophobic fusible carrier has a melting point from about 45 °C to about 90 °C.

82. (new) The oral dosage form of claim 72, further comprising a plasticizer.

83. (new) The oral dosage form of claim 82, wherein the plasticizer is selected from the group consisting of diethyl phthalate, tributyl citrate, triacetin, and mixtures thereof.

84. (new) The oral dosage form of claim 72, further comprising a lubricant.

85. (new) The oral dosage form of claim 84, wherein the lubricant is selected from the group consisting of magnesium stearate, stearic acid, talc, and mixtures thereof.

86. (new) The oral dosage form of claim 72, wherein the dosage form comprises hydromorphone hydrochloride.

87. (new) A method of preparing a sustained-release oral dosage form, comprising:

blending in an extruder hydromorphone or a pharmaceutically acceptable salt thereof together with: (1) a hydrophobic material selected from the group consisting of alkylcelluloses, acrylic and methacrylic acid polymers and copolymers, shellac, zein, hydrogenated castor oil, hydrogenated vegetable oil; and (2) a hydrophobic fusible carrier selected from the group consisting of natural or synthetic waxes, fatty acids, fatty alcohols, and mixtures thereof, the hydrophobic fusible carrier having a melting point between 30-200 °C and being included in an amount sufficient to further slow the release of the hydromorphone;

heating the blend to a temperature sufficient to soften the mixture sufficiently to extrude the same;

extruding the heated mixture as a strand having a diameter from 0.1-5 mm;

cooling the strand; dividing the strand to form non-spheroidal multi-particulates of the extrudate having a length from 0.1-5 mm; and

dividing the non-spheroidal multi-particulates into unit doses,

wherein the oral dosage form, when containing about 8 mg hydromorphone or its pharmaceutically acceptable salt, provides an in-vivo plasma concentration versus time curve (in the fasted state) having an AUC from about 15.83 to about 19.23 ng·hour/ml, which is about 96-132% of the AUC observed when an immediate release formulation of the same dosage is administered, a C_{max} from about 0.52 to about 0.76 ng/ml, which is about 16-21% of the C_{max} observed when an immediate release formulation of the same dosage is administered, and a T_{max} from about 3.9 to about 6.8 hours, which is about 557-971% of the T_{max} observed when an immediate release formulation of the same dosage is administered.

88. (new) A method of preparing a sustained-release oral dosage form, comprising:

blending in an extruder hydromorphone or a pharmaceutically acceptable salt thereof together with: (1) a hydrophobic material selected from the group consisting of alkylcelluloses, acrylic and methacrylic acid polymers and copolymers, shellac, zein, hydrogenated castor oil, hydrogenated vegetable oil; and (2) a hydrophobic fusible carrier selected from the group consisting of natural or synthetic waxes, fatty acids, fatty alcohols, and mixtures thereof, the hydrophobic fusible carrier having a melting point between 30-200 °C and being included in an amount sufficient to further slow the release of the hydromorphone;

heating the blend to a temperature sufficient to soften the mixture sufficiently to extrude the same; extruding the heated mixture as a strand having a diameter from 0.1-5 mm;

cooling the strand; dividing the strand to form non-spheroidal multi-particulates of the extrudate having a length from 0.1-5 mm; and

dividing the non-spheroidal multi-particulates into unit doses,

wherein the oral dosage form, when containing about 8 mg hydromorphone or its pharmaceutically acceptable salt, provides an in-vivo plasma concentration versus time curve (in the fed state) having an AUC from about 16.55 to about 21.47 ng·hour/ml, a C_{max} from about 0.65 to about 0.93 ng/ml, and a T_{max} from about 1.9 to about 4.1 hours.

89. (new) The method of claim 87 or 88, further comprising extruding said heated mixture under vacuum conditions to provide a substantially non-porous extrudate.

90. (new) The method of claim 87 or 88, wherein the hydrophobic fusible carrier has a melting point from about 45 °C to about 90 °C.

91. (new) The method of claim 87 or 88, wherein a unit dose comprising an effective amount of the multi-particulates is compressed into a tablet.

92. (new) The method of claim 87 or 88, wherein a unit dose comprising an effective amount of the multi-particulates is contained within a gelatin capsule.

93. (new) The method of claim 87 or 88, further comprising blending a plasticizer with the hydromorphone or its pharmaceutically acceptable salt, the hydrophobic material, and the hydrophobic fusible carrier prior to heating the blend.

94. (new) The method of claim 93, wherein the plasticizer is selected from the group consisting of diethyl phthalate, tributyl citrate, triacetin, and mixtures thereof.

95. (new) The method of claim 87 or 88, further comprising blending a lubricant with the hydromorphone or its pharmaceutically acceptable salt, the hydrophobic material, and the hydrophobic fusible carrier prior to heating the blend.

96. (new) The method of claim 95, wherein the lubricant is selected from the group consisting of magnesium stearate, stearic acid, talc, and mixtures thereof.

97. (new) The method of claim 87 or 88, wherein the dosage form comprises hydromorphone hydrochloride.